CERTIFICADO ◆ 인증서 ◆ CERTIFICATO ◆ 認証書 ◆ CERTIFICATE ◆ 认证证书 ◆ ZERTIFIKAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Certificate

No. Q8 070242 0008 Rev. 01

Holder of Certificate: **EXCO GmbH**
Adam-Opel-Str. 9-11
67227 Frankenthal
GERMANY

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate:

The Provision of Design and Development Services for Components, Semi-Finished Products and Manufacturing Processes for Medical Devices and In Vitro Diagnostics.
The Provision of Development Services and of Testing and Production Equipment for the Manufacturing of Medical Devices and In Vitro Diagnostics, including Robot-Based Physical Testing for Use within Product Development, Verification or Validation Activities.
The Provision of Regulatory Affairs Services for Medical Devices and In Vitro Diagnostics.
The Provision of Qualification and Validation Services for the Manufacturing of Medical Devices and In Vitro Diagnostics.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q8 070242 0008 Rev. 01

Report No.: 713407294

Valid from: 2026-09-22
Valid until: 2029-09-21

Date, 2026-08-07

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. Q8 070242 0008 Rev. 01

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

EXCO GmbH
Adam-Opel-Str. 9-11, 67227 Frankenthal, GERMANY

See Scope of Certificate

EXCO GmbH
Neugasse 21, 07743 Jena, GERMANY

The Provision of design and development and regulatory affairs services for medical devices and in vitro diagnostics, as well as services for maintenance and process control.

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany